

### **REMARKS/ARGUMENTS**

The foregoing amendments in the specification and claims are of formal nature, and do not add new matter.

Prior to the present amendment, Claims 28-47 were pending in this application and were rejected on various grounds. With this amendment, Claims 28-32, 37 and 41-43 have been canceled without prejudice, Claims 33-36, 38-39 and 44 have been amended, and new Claims 48-54 have been added.

Claims 33-36, 38-40 and 44-54 are pending after entry of the instant amendment. Applicants expressly reserve the right to pursue any canceled matter in subsequent continuation, divisional or continuation-in-part applications.

The amendments to the specification and claims are fully supported by the specification and claims as originally filed and do not constitute new matter. In addition, new Claims 48-54 are fully supported by the specification as originally filed. Support for new Claims 48-54 can be found at least on page 80, lines 3-7, on page 282, lines 12-19 and on page 308, line 38 to page 309, line 7 of the specification.

### **Priority Determination**

The Examiner asserts that the effective filing date for the application is September 4, 2001, the filing date of U.S. Application No. 09/946,374. The Examiner further asserts that only the isolated nucleic acid comprising SEQ ID NO:76 (full length) in this application is supported by the disclosure in Application No. 09/946,374. See page 2, of the instant Office Action.

As discussed below, Applicants rely on the gene amplification assay (Example 143) for patentable utility which was first disclosed in U.S. Provisional Application No. 60/162,506, filed October 29, 1999, priority to which has been claimed in this application.

As will be shown, the disclosure of the instant application, which is similar to that of the earlier-filed application (see Example 20, Provisional Application No. 60/162,506), provides the support required to establish utility for the nucleic acid encoding the PRO1293 polypeptide and

the nucleic acid of SEQ ID NO:76. Accordingly, Applicants submit that the subject matter of the instant claims is supported by the disclosure in Provisional Application No. 60/162,506. Therefore, the effective filing date of this application is October 29, 1999, the filing date of Provisional Application No. 60/162,506.

### **Information Disclosure Statement**

The Examiner notes that the information disclosure statements filed on September 12, 2002 and November 6, 2002 do not give sufficient identifying information because they do not identify each reference by author and publication date. In response, Applicants file herewith, an Information Disclosure Statement listing each reference separately and including authors/inventors, relevant accession numbers and publication dates. Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application.

### **Specification**

The specification has been amended to remove embedded hyperlink and/or other form of browser-executable code. Further, the paragraph beginning at page 513, line 13, has been amended to comply with the provisions of the Budapest Treaty.

### **Claim Rejections – 35 U.S.C. §112, First Paragraph (Enablement)**

Claims 28-47 are rejected under 35 U.S.C. §112, first paragraph, allegedly because "the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims." The Examiner further notes that "the specification, while being enabling for an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO: 76, an isolated nucleic acid comprising the nucleotide sequence which completely hybridizes to the nucleotide sequence set forth in SEQ ID NO:76, does not reasonably provide enablement for an isolated nucleic acid encoding the polypeptide of SEQ ID NO:77 or which encodes variants of SEQ ID NO:77." The Examiner further alleges that "instant specification does not teach how to make or use nucleic

acid [having 80%, 85%, 90%, 95% and 99% sequence identity to the nucleic acid of SEQ ID NO:76]." See page 4 of the instant Office Action.

Without acquiescing to the Examiner's position in the current rejections, and without prejudice to further prosecution of the subject-matter in one or more continuation or divisional applications, Claims 28-32, 37 and 41-43 have been canceled. Applicants respectfully submit that the cancellation of Claims 28-32, 37 and 41-43 renders the rejection of these claims moot. Further, Claim 33, as amended, no longer recites a nucleotide acid sequence encoding the polypeptide of SEQ ID NO: 77.

Based on the instant disclosure, which details how to make and use the claimed nucleic acids and the advanced knowledge in the art at the time of filing, one skilled in the art would know exactly how to make and use the claimed nucleic acids for the diagnosis of lung and colon cancer; for example, by using diagnostic methods based on hybridization to such amplified sequences.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of Claims 33-36, 38-40 and 44-47 under 35 U.S.C. §112, first paragraph.

**Claim Rejections – 35 U.S.C. §112, First Paragraph (Written Description)**

Claims 28-32 and 41-47 are rejected under 35 U.S.C. §112, first paragraph, for alleged lack of sufficient written description. The Examiner asserts that claims drawn to "an isolated nucleic acid that shares 80%, 85%, 90%, 95% or 99% identity to the nucleic acid of SEQ ID NO:76" and to "an isolated nucleic acid which hybridize to nucleic acid encoding a specific polypeptide", but "the instant specification only describes the structure of the nucleic acid of SEQ ID NO:76." Thus, the Examiner notes that in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Applicants submit that the cancellation of Claims 28-32 and 41-43, and amendment to Claim 44 (and, as a consequence, those claims dependent from the same) to be dependent on Claim 33 render the rejection of these claims moot.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of Claims 44-47 under 35 U.S.C. §112, first paragraph.

**Claim Rejections – 35 U.S.C. §112, Second Paragraph**

Claims 41-47 are further rejected under 35 U.S.C. §112, second paragraph, because the term “hybridizes under stringent conditions” recited in Claims 41 and 42 is indefinite.

Without acquiescing to these rejections, Applicants submit that the cancellation of Claims 41-43 renders the rejection of these claims (and, as a consequence, those claims dependent from the same) moot. Accordingly, Applicants request that the rejection of Claims 44-47 under 35 U.S.C. §112, second paragraph, be withdrawn.

**Claim Rejections - 35 U.S.C. §102**

The examiner noted that the priority of the instant application is set at December 6, 2001. As discussed above, Applicants respectfully submit that the effective filing date of the present application is October 29, 1999.

Claims 28-47 are rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Baker *et al.*, WO 200012708, published on March 9, 2000.

Applicants respectfully submit that the cancellation of Claims 28-32, 37 and 41-43 renders the rejection of these claims moot.

As discussed above, Applicants are entitled to an effective filing date of October 29, 1999, and hence, Baker *et al.* is not prior art under 102(a) since its filing date is after the effective priority date of this application.

Accordingly, Applicants respectfully request that rejection to Claims 33-36, 38-40 and 44-47 be withdrawn.

### **CONCLUSION**

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited. Should there be any further issues outstanding, the Examiner is invited to contact the undersigned attorney at the telephone number shown below.

Applicants expressly reserve the right to pursue any canceled subject matter in subsequent continuation, divisional or continuation-in-part applications.

Please charge any additional fees, including fees for additional extension of time, or credit overpayment to Deposit Account No. **08-1641** (referencing Attorney's Docket No. **39780-2830 P1C45**).

Respectfully submitted,

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